UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KAREN TUCKER,

Plaintiff,

v.

TOMMY G. THOMPSON, Secretary of Health & Human Services,

Defendant.

HONORABLE JOSEPH E. IRENAS

CIVIL ACTION NO. 04-3934 (JEI)

OPINION

APPEARANCES:

Karen E. Tucker, Plaintiff *pro se*
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IRENAS, Senior District Judge:

Karen Tucker brings this action pursuant to 42 U.S.C. §§ 1395ff(b) and 405(g) for review of the final determination of the Secretary of Health and Human Services[1] denying her application for reimbursement under Medicare Part B for services rendered to eight patients at the Brazos Valley Geriatric Center in 1996.

[1]Michael O. Leavitt has replaced Tommy G. Thompson as Secretary of Health and Human Services. Pursuant to Fed. R. Civ. P. 25(d), Leavitt is automatically substituted for Thompson as a defendant in this action.

For the following reasons, the Court will affirm the Secretary's decision.

I.

Karen Tucker ("Dr. Tucker") is a podiatrist who provided foot care services to patients at the Brazos Valley Geriatric Center ("BVGC"), a nursing home facility in Texas. (Def. Br. at 9.) Dr. Tucker was not an employee of the nursing home, but contracted with BVGC to provide podiatry services to its residents. (Id.) On July 10, September 11 and November 14, 1996, Dr. Tucker provided treatment to the following eight residents of BVGC: Peggy Bie,[2] Ruth Fowler, Seth Gaston, Irene Royder, Anna Rabun, Lena Solvato, Glenn Lemon and Denman Smith.[3] The residents were insured by Medicare Part B, the voluntary supplemental insurance program.

Dr. Tucker's records state that on July 10, she partially removed ingrown toenails manually and with an electric grinder for all eight patients. She applied an antiseptic to the patients' toenails. For five patients, she removed damaged, overgrown or diseased skin from around the nail bed.[4] She applied topical antibiotics to the toes of three of those

[2]Peggy Bie received services only on July 10, 1996.

[3]Dr. Tucker also treated William Wall and Mary Childs, but received full reimbursement for these services.

[4]Fowler, Gaston, Royder, Salvato and Smith.

patients.[5] For all of the patients except Bie, she repeated these procedures on September 11 and November 14.[6]

Dr. Tucker submited claims for Medicare Part B reimbursement for these services, but her claims were denied by the local Medicare carrier. Dr. Tucker sought review of the carrier's initial determination. Upon review, the carrier again denied her claims. Dr. Tucker requested a hearing before the carrier, which was conducted by Medicare Hearing Officer Bill West on July 25, 1997. West upheld the denial of reimbursement on August 26, 1997. (RR. 89-97.) He concluded that the services rendered by Dr. Tucker were not reimbursable under Medicare Part B because they constituted routine foot care, which is excluded from coverage. (RR. 89-90.) West also found that Dr. Tucker's services did not fall under any of the exceptions to the routine foot care exclusion. (Id.)

Dr. Tucker appealed West's decision.[7] On December 6, 2000, an in-person hearing was held before ALJ Mark Barrett. In decisions dated January 11, 2001, ALJ Barrett concluded that full

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[5]Royder, Salvato and Smith.

[6]Dr. Tucker's records contain inconsistencies in the description of services rendered to each patient on each visit, which are discussed *infra* section IV.

[7]Dr. Tucker's first appeal was denied by ALJ Herbert Green on March 26, 1999. (R. 88.) Dr. Tucker appealed ALJ Green's decision to the Department of Health and Human Services Departmental Appeals Board. (R. 75.) The Appeals Board was unable to retrieve the administrative record from the proceeding before ALJ Green, and so the Board vacated the decision and remanded the case to the ALJ on November 22, 1999. (Id.)

Medicare reimbursement was warranted with respect to services provided to two beneficiaries;[8] partial reimbursement was warranted with respect to services to two other beneficiaries;[9] and reimbursement was not warranted at all with respect to services to six beneficiaries.[10] (RR. 31-35 (Bie); 133-138 (Fowler); 234-38 (Gaston); 336-41 (Royder); 448-53 (Rabun); 557-61 (Solvato); 663-68 (Lemon); 777-81 (Smith).) ALJ Barrett found that Dr. Tucker failed to provide credible contemporaneous medical records that demonstrated medical necessity of these services, as required by Medicare regulations. (Id.) Although Dr. Tucker provided the court with orders signed by the attending physicians that did comport with Medicare standards, these orders were signed one and one half to four years after the services were rendered.

Dr. Tucker appealed ALJ Barrett's decision to the Medicare Appeals Council (MAC), a component of the Departmental Appeals Board. The MAC denied Dr. Tucker's request for review, and ALJ Barrett's decision accordingly stands as the final decision of the Secretary. On August 17, 2004, Dr. Tucker filed a complaint in this Court seeking review of ALJ Barrett's decision.

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[8]The decisions as to William Wall and Mary Childs are not part of the administrative record on appeal because ALJ Barrett determined that the claims should be fully paid.

[9]Anna Rabun and Glenn Lemon.

[10]Peggy Bie; Ruth Fowler; Seth Gaston; Irene Royder; Lena Salvato; and Denman Smith.

II.

Section 405(g) sets forth the standard of review that this Court utilizes in reviewing a final determination of the Secretary. Findings of fact by the Commissioner are conclusive if they are supported by "substantial evidence." 42 U.S.C. § 405(g)(2002)(incorporated into the Medicare statute by 42 U.S.C. § 1395ff(b)(1)(A)). Substantial evidence has been defined as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971) (quoting *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)); *see also Lewis v. Califano*, 616 F.2d 73, 76 (3d Cir. 1980).

This Court's review under Section 405(g) is plenary as to the Secretary's application of the relevant law. *See Krysztoforski v. Chater*, 55 F.3d 857, 858 (3d Cir. 1995). Even if the Secretary's factual findings are supported by substantial evidence, a district court "may review whether the administrative determination was made upon correct legal standards." *Friedberg v. Schweiker*, 721 F.2d 445, 447 (3d Cir. 1983).

It is within this Court's discretion to affirm, modify, or reverse the Secretary's final decision with or without remand. *See* 42 U.S.C. § 405(g); *Podedworny v. Harris*, 745 F.2d 210, 221 (3d Cir. 1984).

III.

A.

Medicare is a national health insurance program for individuals age 65 or older, individuals under age 65 with disabilities, and individuals with end stage renal disease. 42 U.S.C. § 1395 *et seq*. Medicare is administered by the Centers for Medicare & Medicaid Services, a component of the Department of Health and Human Services. Medicare is comprised of four main coverage areas: Part A (inpatient hospital care), Part B (supplementary insurance), Part C (coverage through managed care programs) and prescription drug coverage. Only Part B is relevant to the instant case.

Medicare Part B is a voluntary supplemental insurance program covering outpatient medical services and equipment. 42 U.S.C. §§ 1395j-1395m. Within the categories of covered services, reimbursement to the provider of services is limited to services that are medically "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 C.F.R. § 411.15k. The Medicare Act further provides that "[n]o payment shall be made to any provider of services . . . unless there has been furnished such information as may be necessary in order to determine the amounts due such provider . . . ." 42 U.S.C. § 1395l(e).

The Secretary contracts with private insurance companies, known as carriers, to locally administer the Part B program. 42 U.S.C. § 1395u. Local carriers are delegated the authority to make coverage determinations, determine reimbursement rates and allowable payments, and establish medical review policies. *See id.* Trailblazer Health Enterprises, LLC ("Trailblazer"), was the Part B carrier in Texas when the claims at issue were submitted.

In order to aid Medicare participants and courts in interpreting what constitutes reasonable and necessary for the purposes of obtaining Medicare coverage, the Secretary issues a Medicare Part B Carriers Manual ("MCM"), which includes the agency's interpretation of the Medicare Act. Section 2323 of the MCM states that routine foot care is generally excluded from coverage under Part B. (RR. 135-36.)

Routine foot care includes the cutting or removal of corns and calluses; trimming, cutting, clipping, or debriding of nails; and other hygienic and preventive maintenance care such as cleaning and soaking of feet. (Id.) The MCM provides several exceptions to the routine foot care exclusion, including the treatment of mycotic nails[11] when the physician attending the patient's mycotic condition documents that there is clinical evidence of the mycosis, the patient suffers from pain, secondary

[11]The term "mycotic nails" indicates a fungal infection of the toenails, also referred to as mycosis or onychomycosis.

infection, or in the case of ambulatory patients, marked limitation of ambulation, resulting from the thickening of the infected nail plate. (Id.) Documentation can be "any written information that is required by the carrier in order for services to be covered. Thus, the information submitted with the claims must be substantiated by information found in the patient's medical record." (R. 136.)

Trailblazer requires certain documentation for the reimbursement of services rendered by a podiatrist who has been referred by a patient's attending physician. The Trailblazer Medicare Part B Newsletter No. 135, dated October 26, 1994, specifically discusses podiatry services rendered in nursing homes and states that "foot care provided in nursing home[s] must be supervised by the patient's attending physician." (R. 63.) The Newsletter also states that Medicare services for podiatry provided in nursing homes must be medically necessary, and therefore, documentation of the following information must be maintained in a patient's medical records and be available to Medicare upon request:

> (1) orders for the service are the result of a specific symptom or complaint from the patient or are the result of a finding made by the patient's supervising physician or nursing staff who has reported the finding to the attending physician; (2) orders are in connection with an overall plan of treatment; and (3) services are provided in conjunction with specific anticipated outcomes.

(RR. 63, 890-91.) Trailblazer Newsletter No. 136 discusses the

provision of Part B services to nursing home patients generally and reiterates these requirements for any diagnostic or therapeutic services.[12] (R. 71.)

B.

There is sufficient evidence in the record to support ALJ Barrett's decision that Medicare Part B reimbursement was not warranted for the services in question. ALJ Barrett determined that Dr. Tucker was not entitled to reimbursement for any services rendered to Bie, Fowler, Gaston, Royder, Solvato, and Smith, and that reimbursement was proper only for services rendered to Rabun and Lemon on November 14, 1996. While his decisions in each of the cases are not models of consistency,

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[12] Dr. Tucker was personally aware of the Trailblazer policies through several letters from Medicare officials after the services at issue were rendered. On June 16, 1997, Cecilia Jackson, a Medicare Prepayment Medical Review Specialist, sent Dr. Tucker a letter clarifying Medicare Part B's policy on foot care provided to nursing home patients. (RR. 11-12.) Jackson stated that medical documentation for foot care services provided to nursing home patients should demonstrate (1) that the services are supervised by the patient's attending physician, (2) that the services are provided with an overall plan of care, and (3) specific anticipated outcomes of the services rendered. (Id.) Jackson also stated that valid orders from physicians are also required by Medicare and should contain the date the order was written, the patient's name, the name of the test or type of consultation services requested, and the physician's signature. (Id.)

Also, a letter to Dr. Tucker from James Farris, Regional Administrator for Health Care Financing for the Department of Health and Human Services, dated August 6, 1999, stated that Trailblazer's policy, as evidenced by the newsletters, required that all services provided to nursing home patients be supervised by the attending physician and a standing order alone does not indicate sufficient supervision by the attending physician. (R. 49.) Farris stated that "the medical necessity for and the nature of each service must be clearly documented by the [attending] physician." (Id.) "If the physician refers a nursing home patient to another provider specialty, the order should specify the specific complaint or symptom to be addressed by the treatment." (Id.) This policy applies to *all* services provided in nursing homes, not just podiatry services. (Id.)

there is sufficient evidence to support the conclusion that Dr. Tucker has not demonstrated that her services fit within the mycotic nails exception to the routine foot care exclusion.

The evidence clearly supports ALJ Barrett's conclusion that the physicians' orders in the record do not establish the medical necessity of the services rendered by Dr. Tucker. The orders are uniformly terse, usually stating only "may see podiatrist for eval. + treatment," "consult [with] Dr. Tucker (Podiatry) in one wk," or "consult [with] Dr. Tucker D.P.M." (RR. 24 (Bie); 112, 119, 126 (Fowler); 217, 223, 228 (Gaston); 315, 322, 328, 331 (Royder); 430, 436 (Rabun); 538, 545, 551 (Solvato); 634, 641, 648 (Lemon); 744, 748-49, 751 (Smith).)

These standing orders are insufficient to establish that the services rendered by Dr. Tucker were "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A); *see also Tucker v. U.S.*, Nos. 3:97-CR-337-R, 3:99-CV-2599-R, 2001 WL 1613796 *5 (N.D. Tex. Dec. 13, 2001)(rejecting argument that general standing order in patient's record is sufficient to establish medical necessity for Part B billing purposes). Moreover, in the two instances where the orders provide more detail, they specify services that are not covered by Medicare Part B ("nail trimmings" and "trim this pt. toenails"). (RR. 126, 331.) There is no indication in any of the orders that the patient was referred to Dr. Tucker for treatment of mycotic nails.

ALJ Barrett gave no weight to the so-called clarification orders submitted by the various attending physicians describing their patients' general medical conditions, the particular conditions of the foot to be treated, and attesting to the presence of clinical evidence of mycosis, pain, secondary infection or marked limitation in ambulation. (RR. 25-26 (Bie); 108, 113-14, 120-21, 127-28 (Fowler); 218, 224, 229 (Gaston); 311, 316, 323, 329 (Royder); 431, 437, 443 (Rabun); 539, 546, 552 (Solvato); 635, 642, 649 (Lemon); 750, 752, 760 (Smith).) These clarification orders and letters from the attending physicians were dated a year and a half or more after the services were rendered by Dr. Tucker. They appear to be forms prepared entirely by Dr. Tucker and signed by the appropriate attending physician for each patient.

ALJ Barrett is entitled to make credibility determinations regarding evidence, and a reviewing court must give appropriate deference to those assessments. *See Fargnoli v. Massanari*, 247 F.3d 34, 42-44 (3d Cir. 2001); *Anderson v. Sullivan*, 925 F.2d 220, 222 (7th Cir. 1991)("The Secretary was entitled to give more weight to this contemporaneous medical evidence than to medical opinions based on six or seven years of hindsight."); *Tsoutsouris v. Shalala*, 977 F.Supp. 899, 904-05 (N.D. Ind. 1997)(rejecting argument that submission of after-the-fact affidavits to clarify insufficient contemporaneous medical records precluded ALJ's

determination that podiatrist had not provided adequate documentation to support claim for reimbursement).

Moreover, the patients' medical records corresponding with the service dates at issue here do not contain any contemporaneous evidence that the patients in fact suffered from mycotic nails. The record contains no laboratory evidence of a fungal infection for Salvato, Royder, Gaston, Rabun or Smith.[13] For the other patients, the only laboratory evidence indicating an infection resulted from tests done over a year before Dr. Tucker's services were rendered. (RR. 19 (Bie); 106 (Fowler); 655-56 (Lemon).)

The various items of contemporaneous medical documentation submitted by Dr. Tucker for the service dates at issue for each patient do not establish that the mycotic nails exception is applicable. The record includes laboratory testing requests for all eight patients, but with the exception of a request form for Rabun dated November 14, 1996, the forms contain no details regarding the patients' condition, other than the diagnosis of "onchyomycosis."[14] The forms are more often than not undated and

[13]The laboratory reports included for Royder and Solvato indicate that no fungal infection was detected. (RR. 309; 532.) No reports were included for Gaston, Rabun or Smith.

[14]A comparison of these forms with the November 14 request form for Rabun ("the Rabun form") is illustrative, as ALJ Barrett concluded Dr. Tucker was entitled to reimbursement for services rendered to Rabun on that date. The Rabun form includes a request for a pathology test, in addition to the fungal diagnostic profile requested on the other forms. The Rabun form lists as the chief complaint "[p]ainful infected ingrown toe nail [illegible] foot." The form indicates that Dr. Tucker performed an operation which produced the

no corresponding testing results have been provided. There are no contemporaneous records prepared by anyone other than Dr. Tucker, such as an attending physician or nurse, indicating that the patients suffered from fungal infections of the toeanils.

For each instance in which Dr. Tucker rendered services to a patient, she has submitted typewritten progress notes ("Progress Note") and forms listing the overall plan of care, problem, goals and approaches for the patient ("Overall Plan Form"), as well as a circulatory evaluation form filled out by hand ("Evaluation Form"). These documents do not support the conclusion that Dr. Tucker performed any services other than routine foot care, and indicate that she performed the same procedure (partial removal of ingrown nail plates manually and with an electric grinder) multiple times on the patients, without discussion of the success or failure of the prior procedure. The forms often contain inconsistencies that an ALJ is entitled to consider in determining their probative value.

For Bie, the only contemporaneous evidence in the record related to the services rendered by Dr. Tucker are three forms dated July 10, 1996. (RR. 21, 22, 23.) Other than Dr. Tucker's unsupported statement that Bie suffered from onychomycosis, the Progress Note, Overall Plan Form and Evaluation Form indicate only that Dr. Tucker treated Bie's painful thickened ingrown

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specimen to be tested.

toenails, a service within the routine foot care exclusion. (Id.) The Progress Note and Overall Plan Form contain nearly identical language to those submitted for the other patients, and appear in many respects to be exact copies. Notably, the Overall Plan Form fails to include a deformity of one of Bie's big toes that was indicated in the Progress Note, an inexplicable inconsistency. The only handwritten form, the Evaluation Form, does not include any notations indicating that Bie had a fungal infection of the toenails. (R. 23.)

The documentation of the services rendered to Fowler is similarly insufficient. For each of the three dates of service (July 10, September 11 and November 14, 1996), Dr. Tucker submits Progress Notes, Overall Plan Forms and Evaluation Forms. (RR. 109-11, 116-18, 123-25.) As with Bie, there is no indication from these records that Fowler had a fungal infection of the toenails, other than Dr. Tucker's unsupported diagnosis. It appears that Fowler suffered from painful thickened ingrown toenails that made it difficult for her to walk. Interestingly, the forms list Fowler as having one structural deformity of the toe on July 10 and November 14, but mention an entirely different deformity on September 11. The Evaluation Forms contain no indication of a fungal infection.

For the services rendered to Gaston on July 10, September 11 and November 14, 1996, Dr. Tucker submitted Progress Notes and

Evaluation Forms for all three dates and Overall Plan Forms for the first two dates. (RR. 214-16, 220-22, 226-27.) These forms provide no support for Dr. Tucker's conclusory diagnosis of onychomycosis, and indicate only that Dr. Tucker removed ingrown toenails. In fact, the Evaluation Form from July 10 bears a notation that appears to indicate that there was no fungal infection. The September 11 Evaluation Form states that Gaston no longer needed podiatry services, yet Dr. Tucker saw Gaston again on November 14.

The Progress Notes, Overall Plan Forms and Evaluation Forms submitted for Royder contain inconsistencies that undermine their probative value. (*See* RR. 312-14, 319-21, 325-27.) As with Fowler, the Progress Notes from July 10 and November 14 list Royder as having one structural deformity of the toe, but on September 11 the Progress Note lists a different deformity. The forms for the July 10 and September 11 indicate that Dr. Tucker removed the same toenail on both occasions. The September 11 Progress Note indicates that the toe was healing well, but the Evaluation Form states that it was growing back with fungus. The November 14 forms make no reference to the removal of this toenail or the healing process. On all three dates the forms indicate that Dr. Tucker partially removed *all* of the toenails, but also specify that Dr. Tucker removed a particular toenail.

Dr. Tucker submitted Progress Notes, Overall Plan Forms and

Evaluation Forms for the July 10 and September 11 services rendered to Rabun, as well as the November 14 services for which ALJ Barrett determined she was entitled to reimbursement. (RR. 427-29, 433-35, 439-41.) The forms for July 10 and September 11 contain little specific detail, except to state that Rabun had ingrown toenails with fungal infections, and that Dr. Tucker partially removed the nails from each toe. By contrast, the November 14 Progress Note indicates that Rabun had webbing between the second and third toes of her right foot and a bruise on her foot. On November 14, Dr. Tucker removed the nail from Rabun's right big toe and submitted a request for laboratory testing with significant detail regarding the procedure and the specimen biopsied. The prior forms make no mention of the webbing or detail the specific problem with Rabun's right big toe. These inconsistencies highlight the lack of clinical evidence of mycotic nails in the records for the July 10 and September 11 serivces rendered to Rabun.

For the services rendered to Salvato on July 10, September 11 and November 14, Dr. Tucker submitted Progress Notes, Overall Plan Forms and Evaluation Forms. (RR. 534-37, 542-44, 549-50, 606.) Dr. Tucker stated that Salvato had ingrown toenails with fungal infections, and that she partially removed all of Salvato's toenails on each service date. The forms provide no specific details or support for the onychomycosis diagnosis, but

provide more information on foot conditions other than mycotic nails, such as hammer toes and several wounds on Salvato's leg and feet. Treatment of these conditions does not fit within any exception to the routine foot care exclusion.

As with Rabun, Dr. Tucker has submitted Progress Notes, Overall Plan Forms and Evaluation Forms for the services rendered to Lemon on July 10, September 11 and November 14, although ALJ Barrett determined she was entitled to reimbursement for the November 14 services.[15] (RR. 638-40, 643, 646-47, 657-59.) These forms also reveal discrepancies. While all of the forms state that Lemon had ingrown mycotic toenails which Dr. Tucker partially removed on all three dates, only the November 14 forms indicate that Lemon suffered from hammer toes. On September 11 and November 14, the forms state that Lemon also suffered from a painful bunion, but the July 10 form makes no mention of this deformity. There are no laboratory testing requests in the record for any of the three dates of service.

The Progress Notes, Overall Plan Forms and Evaluation Forms submitted for the services rendered to Smith on July 10, September 11 and November 14 contain no details regarding Dr. Tucker's diagnosis of mycotic nails. (RR. 756-58, 763-65, 769-70.) The Evaluation Form from September 11 includes slightly

[15]The Court sees little difference in the documentation provided for the reimbursed November 14 services and the denied July 10 and September 11 claims. However, ALJ Barrett's decision regarding the November 14 service date is not before this Court.

more detail of Smith's foot conditions but notably makes no mention of fungal infection. All that can be concluded from these forms is that on each date, Dr. Tucker partially removed Smith's ingrown toenails, a service not excepted from the routine foot care exclusion.

A review of the record indicates that there is substantial evidence to support ALJ Barrett's conclusion that Dr. Tucker was not entitled to reimbursement under Medicare Part B for services rendered to these patients on July 10, September 11 and November 14, 1996. Neither the orders of the attending physicians nor the patients' medical records contain any contemporaneous documentation that any of the patients suffered from onychomycosis or that the services rendered by Dr. Tucker were "necessary and reasonable." 42 U.S.C. § 1395y(a)(1)(A).

IV.

For the aforementioned reasons, the Court will affirm the Secretary's final decision denying Dr. Tucker's applications for reimbursement. The Court will issue an appropriate order.

Dated: January 9th, 2006

s/Joseph E. Irenas
JOSEPH E. IRENAS, S.U.S.D.J.